

CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

Unsuccessful applicants will receive notification of the results of the application review by mail.

VI.2. Administrative and National Policy Requirements

45 CFR Part 74 and Part 92

For more information on the Code of Federal Regulations, see the National Archives and Records Administration at the following Internet address: <http://www.access.gpo.gov/nara/cfr/cfr-table-search.htm>.

The following additional requirements apply to this project:

- AR-1, Human Subjects Requirements.

- AR-2, Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research.

- AR-7, Executive Order 12372 Review.

- AR-10, Smoke-Free Workplace Requirements.

- AR-11, Healthy People 2010.

- AR-12, Lobbying Restrictions.

- AR-15, Proof of Non-Profit Status (If applicable).

- AR-22, Research Integrity.

- AR-24, Health Insurance Portability and Accountability Act Requirements.

Additional information on these requirements can be found on the CDC Web site at the following Internet address: <http://www.cdc.gov/od/pgo/funding/ARs.htm>.

VI.3. Reporting

You must provide CDC with an original, plus two hard copies of the following reports:

1. Interim progress report, (use form PHS 2590, OMB Number 0925-0001, rev. 5/2001 as posted on the CDC website) no less than 90 days before the end of the budget period. The progress report will serve as your non-competing continuation application, and must contain the following elements:
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 - d. Budget.
 - e. Additional Requested Information.
 - f. Measures of Effectiveness.

2. Financial status report and annual progress report, no more than 90 days after the end of the budget period.

3. Final financial and performance reports, no more than 90 days after the end of the project period.

These reports must be mailed to the Grants Management Specialist listed in the "Agency Contacts" section of this announcement.

VII. Agency Contacts

For general questions about this announcement, contact: Technical Information Management Section, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2700.

For scientific/research issues, contact: Mr. Gary Edgar, Project Officer, CDC, National Immunization Program, 1600 Clifton Road, NE., Mailstop E-52, Atlanta, GA 30333, Phone: 404-639-8787, E-mail: GWE1@CDC.GOV.

For questions about peer review, contact: Ms. Beth Gardner, Scientific Review Administrator, CDC, National Immunization Program, 1600 Clifton Road, NE., Mailstop E-05, Atlanta, GA 30333, Phone: 404-639-6101, E-mail: BGardner@CDC.GOV.

For financial, grants management, or budget assistance, contact: Jesse L. Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: 770-488-2747, E-mail: jtr4@CDC.GOV.

VIII. Other Information

National Immunization Program, Centers for Disease Control and Prevention, Internet address: <http://www.cdc.gov/nip>.

Dated: March 24, 2004.

Edward J. Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04-7013 Filed 3-25-04; 1:52 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Evaluation of Parents Claiming Exemptions to School Entry Immunization Requirements

Announcement Type: New.
Funding Opportunity Number: 04091.
Catalog of Federal Domestic Assistance Number: 93.185.

Key Dates:
Letter of Intent Deadline: April 29, 2004.

Application Deadline: June 1, 2004.

I. Funding Opportunity Description

Authority: Public Health Service Act, Section 317(k)(1), 42 U.S.C. 247b(k)(1), as amended.

Purpose: The purpose of the program is to characterize the attitudes of parents who elect to claim immunization exemptions for their children and to develop a method that can be used to assess immunization exemption rates, attitudes, and practices among parents and providers within a particular geographic area.

Immunizations are considered one of the most effective means to prevent serious, life-threatening diseases. Currently, all states have laws that require proof of immunization for school entrance. Immunization exceptions exist in all states and may be claimed for a variety of reasons including medical, religious, or philosophical reasons.

In recent years, some states have experienced an increase in the rate of immunization exemptions claimed. Previous research suggests that the rate of immunization exemptions may be related to several factors including the amount of effort needed to claim an exemption compared to the amount of effort needed to actually fulfill the immunization requirement. Anecdotal reports claim that the increase may be due to new vaccine requirements (*i.e.* hepatitis B and varicella) and to increasing parental opposition to vaccination, potentially spurred by vaccine safety concerns.

Reasons for claiming an exemption have not been thoroughly evaluated. When a parent claims an exemption it is unknown if the parent opposes all vaccines, one particular vaccine series, or simply does not have time to bring his/her child to a healthcare provider to get the last dose of vaccine in a series. It is also unknown what role the physician plays (if any) in a parent's decision to claim an exemption.

Understanding why parents claim exemptions can help the Centers for Disease Control and Prevention (CDC) to ensure that exemptions are used appropriately and that parents are knowledgeable about their options.

This program addresses the "Healthy People 2010" focus area of Immunization and Infectious Diseases.

Measurable outcomes of the program will be in alignment with the performance goal for the Centers for Disease Control and Prevention's National Immunization Program (NIP) to reduce the number of indigenous cases of vaccine-preventable diseases.

Research Objectives: To identify reasons for immunization exemptions

from the parent and provider perspectives and provide a better understanding of why immunization exemptions are claimed.

Specific research objectives:

1. Evaluate the rate of exemptions over time within a specific geographic area (at least one state) with respect to:

a. Geographic distribution of exemptions (e.g., county, school district, school grade etc.)

b. Timing of introduction of new vaccine requirements or legislation.

c. Reports of adverse health events purportedly associated with vaccines or vaccine components.

2. Select schools with high or increasing rates of exemptions within a particular geographic area and identify, characterize, and describe the types of immunization exemptions claimed by parents and their providers.

a. For parents, describe and compare parents claiming an exemption for their child to parents not claiming exemptions.

b. Evaluate and compare the health care providers of parents claiming and not claiming an exemption.

3. Evaluate the research project area to determine the disease risk or outbreak potential from vaccine-preventable diseases.

4. Based on findings from objectives #1, #2, and #3, develop a method (including data collection instruments and analytical tools) that can be used to assess immunization exemption rates, attitudes, and practices among parents and providers.

Activities:

Awardee activities for this program are as follows:

1. Develop methods for analyzing state exemption data.

2. Develop appropriate state selection criteria. Select and enroll states.

3. Develop methods for identifying, sampling, and surveying parents who have and have not claimed an exemption for their child. Survey information should include demographic characteristics, including vaccination status of children; attitudes towards vaccination, including perceived benefits and risks; sources of vaccine information; reasons for claiming (or not) an exemption. Include a description of the survey instrument, statistical analysis, and outcome measures.

4. Develop methods for identifying, sampling, and surveying healthcare providers of children whose parents have and have not claimed an exemption. Survey data should include opinions regarding vaccination and exemptions; the role they play (if any) in influencing parents to opt for/against

immunization/exemption; and, whether they are claiming medical exemptions for their patients based on parental pressure. Include a description of the survey instrument, statistical analysis, and outcome measures.

5. Develop a method that can be used to assess immunization exemption rates, attitudes, and practices among parents, as described in Specific Research Objective 3 above.

6. Develop a method that can be used to assess immunization exemption rates, attitudes, and practices among providers, as described in Specific Research Objective 4 above.

7. Collect and analyze data.

8. Collaboratively disseminate research findings in peer reviewed publications and for use in determining national policy.

In a cooperative agreement, CDC staff is substantially involved in the program activities, above and beyond routine grant monitoring.

CDC Activities for this program are as follows:

1. Provide CDC investigator(s) to monitor the cooperative agreement as project officer(s).

2. Participate as active project team members in the development, implementation and conduct of the research project and as coauthors of all scientific publications that result from the project.

3. Provide technical assistance on the selection and evaluation of data collection and data collection instruments.

4. Assist in the development of research protocols for Institutional Review Boards (IRB) review. The CDC IRB will review and approve the project protocol initially and on at least an annual basis until the research project is completed.

5. Contribute subject matter expertise in the areas of epidemiologic methods and statistical analysis, and survey research consultation.

6. Participate in the analysis and dissemination of information, data and findings from the project, facilitating dissemination of results.

7. Serve as liaisons between the recipients of the project award and other administrative units within the CDC.

8. Facilitate an annual meeting between awardee and CDC to coordinate planned efforts and review progress.

II. Award Information

Type of Award: Cooperative Agreement.

CDC involvement in this program is listed in the Activities Section above.

Fiscal Year Funds: 2004.

Approximate Total Funding: \$200,000.

Approximate Number of Awards: One.

Approximate Average Award: \$200,000 (This amount is for the first 12-month budget period, and includes both direct and indirect costs).

Floor of Award Range: None.

Ceiling of Award Range: \$200,000.

Anticipated Award Date: August 15, 2004.

Budget Period Length: 12 months.

Project Period Length: Two years.

Throughout the project period, CDC's commitment to continuation of awards will be conditioned on the availability of funds, evidence of satisfactory progress by the recipient (as documented in required reports), and the determination that continued funding is in the best interest of the Federal Government.

III. Eligibility Information

III.1. Eligible Applicants

Applications may be submitted by public and private nonprofit organizations and by governments and their agencies, such as:

- Public nonprofit organizations
- Private nonprofit organizations
- Universities
- Colleges
- Research institutions

III.2. Cost Sharing or Matching

Matching funds are not required for this program.

III.3. Other

If you request a funding amount greater than the ceiling of the award range, your application will be considered non-responsive, and will not be entered into the review process. You will be notified that your application did not meet the submission requirements.

Individuals Eligible to Become Principal Investigators: Any individual with the skills, knowledge, and resources necessary to carry out the proposed research is invited to work with their institution to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for CDC programs.

Note: Title 2 of the United States Code section 1611 states that an organization described in section 501(c)(4) of the Internal Revenue Code that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, or loan.

IV. Application and Submission Information

IV.1. Address To Request Application Package

To apply for this funding opportunity, use application form PHS 398 (OMB number 0925-0001 rev. 5/2001). Forms and instructions are available in an interactive format on the CDC web site, at the following Internet address: <http://www.cdc.gov/od/pgo/forminfo.htm>.

Forms and instructions are also available in an interactive format on the National Institutes of Health (NIH) Web site at the following Internet address: <http://grants.nih.gov/grants/funding/phs398/phs398.html>.

If you do not have access to the Internet, or if you have difficulty accessing the forms on-line, you may contact the CDC Procurement and Grants Office Technical Information Management Section (PGO-TIM) staff at (770) 488-2700. Application forms can be mailed to you.

IV.2. Content and Form of Application Submission

Letter of Intent (LOI): A LOI is required and must be written in the following format:

- Maximum number of pages: Three
- Font size: 12-point un-reduced
- Single spaced
- Paper size: 8.5 by 11 inches
- Page margin size: One inch
- Printed only on one side of page
- Written in plain language, avoid jargon

Your LOI must contain the following information:

- Descriptive title of the proposed research
- Name, address, E-mail address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating institutions
- Number and title of this Program Announcement (PA)
- Summary of proposed activities and description of study design, methods, and analyses.

Application: Follow the PHS 398 application instructions for content and formatting of your application. For further assistance with the PHS 398 application form, contact PGO-TIM staff at (770) 488-2700, or contact GrantsInfo, Telephone (301) 435-0714, E-mail: GrantsInfo@nih.gov.

The Program Announcement Title and number must appear in the application.

You must include a research plan with your application. The research plan should be double spaced and no more than 25 pages.

Your application will be evaluated on the criteria listed under Section V. Application Review Information, so it is important to follow them, as well as the Research Objectives and the Administrative and National Policy Requirements (AR's), in laying out your research plan.

Your research plan should address activities to be conducted over the entire project period. The research plan should consist of the following information:

1. **Abstract.** It is especially important to include an abstract that reflects the project's focus, because the abstract will be used to help determine the responsiveness of the application.

2. **Program Goals and Objectives.** Describe the goals and objectives the proposed research is designed to achieve in the short and long term. Specific research questions and hypotheses should be included.

3. **Program Participants.** Provide a justification and description of the specific state and schools targeted, including past and current exemption data and demographic and geographic characteristics. In addition, the proposal should provide evidence that the recipient has the capacity and state or local support necessary to recruit participants, including providers and parents of children sampled at participating schools. Describe how the study sample(s) is defined. A description of how recruitment, retention and referral of participants will be handled should also be included.

4. **Methods.** Describe methods and sources of data for assessing trends in exemption data. Describe methods for sampling children (with exemptions and without) from participating schools. Describe topic areas and potential questions to be examined with providers and parents. If any materials are not extant, the methods and timeframe for measure development and pilot testing should be given.

5. **Project Management.** Provide evidence of the expertise, capacity, and support necessary to successfully implement the project. Each existing or proposed staff position for the project should be described by job title, function, general duties, level of effort, and allocation of time. Management operation principles, structure, and organization should also be noted.

6. **Collaborative Efforts.** List and describe any current and proposed collaborations with government and health agencies or other researchers that will impact this project. Include letters of support and memoranda of understanding that specify the nature of

past, present, and proposed collaborations, and the products/services/activities that will be provided by and to the applicant.

7. **Data Sharing and Release:** Describe plans for the sharing and release of data.

8. **Budget.** Applications must be submitted in a modular grant format. The modular grant format simplifies the preparation of the budget in these applications by limiting the level of budgetary detail. Applicants request direct costs in \$25,000 modules. Section C of the research grant application instructions for the PHS 398 (rev. 5/2001) is available at: <http://grants.nih.gov/grants/funding/phs398/phs398.html>. This includes step-by-step guidance for preparing modular grants. Additional information on modular grants is available at: <http://grants.nih.gov/grants/funding/modular/modular.htm>.

Your research plan should address activities to be conducted over the entire project period.

You are required to have a Dun and Bradstreet Data Universal Numbering System (DUNS) number to apply for a grant or cooperative agreement from the Federal Government. Your DUNS number must be entered on line 11 of the face page of the PHS 398 application form. The DUNS number is a nine-digit identification number, which uniquely identifies business entities. Obtaining a DUNS number is easy and there is no charge. To obtain a DUNS number, access <http://www.dunandbradstreet.com> or call 1 (866) 705-5711. For more information, see the CDC web site at: <http://www.cdc.gov/od/pgo/funding/pubcomm.htm>.

Additional requirements that may require you to submit additional documentation with your application are listed in section "VI.2. Administrative and National Policy Requirements."

Administrative and National Policy Requirements."

IV.3. Submission Dates and Times

LOI Deadline Date: April 29, 2004.

A letter of Intent (LOI) is required for this Program Announcement. The LOI will not be evaluated or scored. Your letter of intent will be used to estimate the potential reviewer workload and to avoid conflicts of interest during the review. If you do not submit a LOI, you will not be allowed to submit an application.

Application Deadline Date: June 1, 2004.

Explanation of Deadlines:

Applications must be received in the CDC Procurement and Grants Office by 4 p.m. Eastern Time on the deadline date. If you send your application by the

United States Postal Service or commercial delivery service, you must ensure that the carrier will be able to guarantee delivery of the application by the closing date and time. If CDC receives your application after closing due to: (1) carrier error, when the carrier accepted the package with a guarantee for delivery by the closing date and time, or (2) significant weather delays or natural disasters, you will be given the opportunity to submit documentation of the carriers guarantee. If the documentation verifies a carrier problem, CDC will consider the application as having been received by the deadline.

This announcement is the definitive guide on application submission address and deadline. It supersedes information provided in the application instructions. If your application does not meet the deadline above, it will not be eligible for review, and will be discarded. You will be notified that your application did not meet the submission requirements.

CDC will not notify you upon receipt of your application. If you have a question about the receipt of your application, first contact your courier. If you still have a question, contact the PGO-TIM staff at: (770) 488-2700. Before calling, please wait two to three days after the application deadline. This will allow time for applications to be processed and logged.

IV.4. Intergovernmental Review of Applications

Your application is subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (EO) 12372. This order sets up a system for state and local governmental review of proposed federal assistance applications. You should contact your state single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications, and to receive instructions on your state's process. Click on the following link to get the current SPOC list: <http://www.whitehouse.gov/omb/grants/spoc.html>.

IV.5. Funding Restrictions

If you are requesting indirect costs in your budget, you must include a copy of your indirect cost rate agreement. If your indirect cost rate is a provisional rate, the agreement should be less than 12 months of age.

Awards will not allow reimbursement of pre-award costs.

IV.6. Other Submission Requirements

LOI Submission Address: Submit your LOI by express mail, delivery service, fax, or E-mail to:

Ms. Beth Gardner, Scientific Review Administrator, CDC, National Immunization Program, 1600 Clifton Road NE., Mailstop E-05, Atlanta, GA 30333, Phone: (404) 639-6101, Fax: (404) 639-0108, Email: BGardner@CDC.GOV.

Application Submission Address: Submit the original and five hard copies of your application by mail or express delivery service to:

Technical Information Management-PA# 04091, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341.

Applications may not be submitted electronically at this time.

V. Application Review Information

V.1. Criteria

You are required to provide measures of effectiveness that will demonstrate the accomplishment of the various identified objectives of the cooperative agreement. Measures of effectiveness must relate to the performance goals stated in the "Purpose" section of this announcement. Measures must be objective and quantitative, and must measure the intended outcome. These measures of effectiveness must be submitted with the application and will be an element of evaluation.

The goals of CDC-supported research are to advance the understanding of biological systems, improve the control and prevention of disease and injury, and enhance health. In the written comments, reviewers will be asked to evaluate the application in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals.

The scientific review group will address and consider each of the following criteria in assigning the application's overall score, weighting them as appropriate for each application. The application does not need to be strong in all categories to be judged likely to have major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative, but is essential to move a field forward.

The criteria are as follows:

Significance: Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support?

Additional Review Criteria: In addition to the above criteria, the following items will be considered in the determination of scientific merit and priority score:

- Applicants must have an established relationship with the state immunization program and they must provide documentation of support from the state immunization program.
- Experience with state immunization exemption rate data and ability to justify increasing exemption rates in the selected state(s).
- Ability to perform immunization-related research as demonstrated by peer-reviewed publications in the field.

Protection of Human Subjects from Research Risks: Does the application adequately address the requirements of Title 45 CFR part 46 for the protection of human subjects? This will not be scored; however, an application can be disapproved if the research risks are sufficiently serious and protection against risks is so inadequate as to make the entire application unacceptable.

Inclusion of Women and Minorities in Research: Does the application adequately address the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research? This includes: (1) The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation; (2) The proposed justification when representation is limited or absent; (3) A statement as to whether the design of the study is adequate to measure differences when warranted; and (4) A statement as to

whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

Budget: The reasonableness of the proposed budget and the requested period of support in relation to the proposed research.

V.2. Review and Selection Process

Applications will be reviewed for completeness by the Procurement and Grants Office (PGO), and for responsiveness by NIP. Incomplete applications and applications that are non-responsive to the eligibility criteria will not advance through the review process. Applicants will be notified that their application did not meet submission requirements.

Applications that are complete and responsive to the PA will be evaluated for scientific and technical merit by an appropriate peer review group or charter study section convened by NIP in accordance with the review criteria listed above. As part of the initial merit review, all applications may:

- Undergo a process in which only those applications deemed to have the highest scientific merit, generally the top half of the applications under review, will be discussed and assigned a priority score.

- Receive a written critique.
- Receive a second level programmatic review by a NIP panel.

Award Criteria: Criteria that will be used to make award decisions include:

- Scientific merit (as determined by peer review)
- Availability of funds
- Programmatic priorities

V.3. Anticipated Announcement and Award Dates

Anticipated Application Deadline Date: May 2004.

Anticipated Award Date: August 2004.

VI. Award Administration Information

VI.1. Award Notices

Successful applicants will receive a Notice of Grant Award (NGA) from the CDC Procurement and Grants Office. The NGA shall be the only binding, authorizing document between the recipient and CDC. The NGA will be signed by an authorized Grants Management Officer, and mailed to the recipient fiscal officer identified in the application.

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Mr. Gary Edgar, Extramural Project Officer, CDC, National Immunization Program, 1600 Clifton Road NE., Mailstop E-52, Atlanta, GA 30333, Phone: (404) 639-8787, E-mail: GWE1@CDC.GOV.

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For financial, grants management, or budget assistance, contact:

Jesse L. Robertson, Grants Management Specialist, CDC Procurement and Grants Office, 2920 Brandywine Road, Atlanta, GA 30341, Telephone: (770) 488-2747, E-mail: jtr4@CDC.GOV.

VIII. Other Information

National Immunization Program, Centers for Disease Control and Prevention, Internet address: <http://www.cdc.gov/nip>.

Dated: March 24, 2004.

Edward J. Schultz,

Acting Director, Procurement and Grants Office, Centers for Disease Control and Prevention.

[FR Doc. 04-7015 Filed 3-25-04; 1:52 pm]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Economic Studies of Vaccines and Immunization Policies, Programs, and Practices

Announcement Type: New.
Funding Opportunity Number: 04092.
Catalog of Federal Domestic Assistance Number: 93.185.

Key Dates:

Letter of Intent Deadline: April 29, 2004.

Application Deadline: June 1, 2004.

SPOC Notification Deadline: April 29, 2004. For more information, see section "IV.4. Intergovernmental Review of Applications."